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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,354	07/20/2001	Kevin A. Jarrell	2003320-0032	2372
7590 11/20/2003 Brenda Herschbach Jarrell, Choates, Hall & Stewart Exchange Place 53 State Street Boston, MA 02109			EXAMINER VOGEL, NANCY T	
			ART UNIT 1636	PAPER NUMBER

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,354	JARRELL ET AL.	
	Examiner	Art Unit	
	Nancy Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1 & 2</u> . | 6) <input checked="" type="checkbox"/> Other: <i>Notice to Comply</i> . |

DETAILED ACTION

Claims 1-11 are pending in the case. Receipt of the Response on 10/16/03 is hereby acknowledged.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-5 in Paper No. 10/16/03 is acknowledged. It is noted that claim 11 was omitted from applicant's response, presumably by oversight.

Claims 6-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10/16/03.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/225,990, filed 1/5/99, and 09/897,712, filed 6/26/01. A reference to

the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included. It is noted that although the applications are stated in the first sentence of the specification, the relationship to the instant specification has not been set forth.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A

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priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Specification

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Sequence compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements

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of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. For instance, there are sequences on page 31, 32, 34, 36, 37 and Figure 11. These and all sequences in the specification must be listed in the Sequence Listing and must comply with the requirements of 37 CFR 1.821-1.825.

Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Information Disclosure Statement

The information disclosure statement filed 2/19/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the references which have been crossed through have not been considered because no copy was received.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodgson et al. (WO 98/38326) (cited by applicant).

Hodgson et al. disclose a method of preparing a vector, comprising providing at least two isolated nucleic acid molecules, each of which contains a portion of vector sequence; providing at least one isolated nucleic acid molecule containing insert sequence, and admixing the nucleic acid molecules with one another under linkage conditions so that a hybrid molecule in which each of the isolated molecules is linked together is produced (see Example 1 and 2, pages 35-40, Fig. 8). The reference teaches introducing the vector into a cell (see page 36, lines 3-19, and page 40, line 6-24).

Claims 1, 2, 4, 5 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Huse et al. (US Pat. No. 5,128,256).

Huse et al. disclose a method of preparing a vector, comprising providing at least two isolated nucleic acid molecules, each of which contains a portion of vector sequence, providing at least one isolated insert sequence, and admixing the nucleic acid molecules with one another under linkage conditions so that a hybrid molecule in which each of the isolated molecules is linked together is produced (see Fig. 3A and 3B, which shows ligations of two vector fragments and one insert fragment, and col. 14, lines 14 – col. 17, line 53). The isolated nucleic acid molecules each contain at least one overhang that is complementary with an overhang on at least one of the other molecules. The vector is introduced into a cell (see col. 15, lines 21-33). The vector

elements contain replication elements, expression elements, vector detection elements, and polylinker elements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huse et al. or Hodgson et al. in view of Jarrell (US Pat. 5,498,531, "Jarrell '531") or Jarrell (US Pat. No. 5,780,272 "Jarrell '272").

Huse et al. or Hodgson et al. are cited essentially for the reasons set forth above. The difference between the references and the instant application is that the nucleic acid molecules each contain at least one intronic element that is characterized by an

ability to trans-splice with a compatible intronic element on at least one of the other molecules.

However, by applicants' admission at page 23, lines 9-18 of the instant specification, Jarrell '531 and Jarrell '272 teach methods of preparing vectors comprising providing at least two nucleic acid molecules that contain intronic elements having an ability to trans-splice with each other.

It would have been obvious for one of ordinary skill in the art to have modified the methods of preparing vectors comprising providing at least two nucleic acids having a portion of vector sequence and an insert sequence, and admixing them under linkage conditions, by adding intronic elements to at least two of the nucleic acids, such that trans-splicing can take place between them, as taught by Jarrell '531 and Jarrell '272, in order to efficiently manipulate nucleic acids by specific cleavage and ligation (see column 2, line 33- column 3, line 40 of Jarrell '531, and col. 2, line 39 – col. 3, line 45 of Jarrell '272). One would have been motivated to do so in order to obtain the benefits of ease of manipulation of said nucleic acids, including joining said nucleic acids and eliminating non-essential regions, as taught by Jarrell '531 and Jarrell '272.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

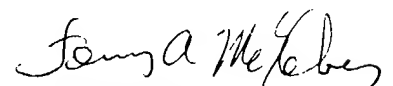
Claim 3 is vague and indefinite in its recitation of "intronic element", since it is not clear what is intended by this phrase. Introns are non-coding sequences which are spliced out of the transcribed RNA molecule, and which contain splice consensus signals, but it is not clear what applicant intends that the recited "intronic element" includes. In the interest of compact prosecution it has been assumed that the term defines an intron containing splicing recognition sites.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ntv


TERRY MCKELVEY
PRIMARY EXAMINER